PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Wei-Wei Zhang
Jack A. Roth

Serial No.: 09/413,109

Filed: October 6, 1999

For: METHODS FOR THE ADMINISTRATION OF ADENOVIRUS p53 (AS AMENDED)

Group Art Unit: 1636

Examiner: Guzo, D.

Atty. Dkt. No.: INRP:087USD1/GNS

THIRD REQUEST FOR CORRECTED FILING RECEIPT

Commissioner for Patents
Washington, D.C. 20231

Sir:

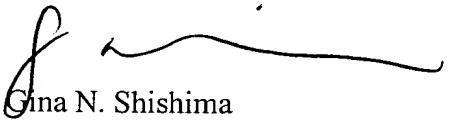
A corrected filing receipt is hereby requested in view of the error which appears in the original. A photocopy of the most recent filing receipt with errors noted in red is provided. Applicants filed a Second Request for Corrected Filing Receipt on January 4, 2000 but received no filing receipt. This request supersedes the second request.

There is an error in the Continuing Data. Please delete the Continuing Data as stated and insert the following: -- **this application is a divisional of co-pending application Serial No. 08/145,826 filed October 29, 1993 which is a continuation-in-part of 07/960,513 filed October 13, 1992 --.**

Because the error is not due to any error by Applicants, no fee is believed to be due in connection with the filing of this document. However, should any fee under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to this document, the Commissioner is hereby authorized to deduct said fee from Fulbright & Jaworski Deposit Account No.: 50-1212/10012509/GNS. In support of the requested correction, Applicants attach hereto a copy of the Preliminary Amendment filed October 6, 1999.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,



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FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
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Date: March 19, 2001

PTO-103X
(Rev. 6-99)

FILING RECEIPT

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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
09/413,109	10/06/99	1636	$1,426.00	INRP;087/SHS	9	57	3

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Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts of Application" ("Missing Parts Notice") in this application, please submit any corrections to this Filing Receipt with your reply to the "Missing Parts Notice." When the PTO processes the reply to the "Missing Parts Notice," the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s) WEI-WEI ZHANG, SUGAR LAND, TX; JACK A. ROTH, HOUSTON, TX.

Divisional

CONTINUING DATA AS CLAIMED BY APPLICANT-
THIS APPLN IS A ~~CON~~ OF 08/145,826 10/29/93
WHICH IS A CONTINUATION-IN-PART OF 07/960,513 10/13/92

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 10/29/99
TITLE
RECOMBINANT P53 ADENOVIRUS METHODS AND COMPOSITIONS

PRELIMINARY CLASS: 514

REC'D. - A. W. & D.

DEC 06 1999

HOUSTON DOCKETING DEPT.

INRP087---

DOCKETED ☒ UPDATED ☐
Previously ____ Not Required ____
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By: ____ Checked ____

DATA ENTRY BY: LOVER, ANTHONY TEAM: 08 DATE: 11/30/99

(See reverse for new important information)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Wei-Wei Zhang and Jack Roth	§	
DIV of Serial No. 08/145,826	§	Prior Group Art Unit: 1805
Filed: Concurrently Herewith	§	Prior Examiner: Guzo, D.
For: SYSTEMIC ADMINISTRATION OF ADENOVIRUS p53	§	Atty. Dkt.: INRP:087/SHS

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NUMBER EL 259186668 US
DATE OF DEPOSIT October 6, 1999

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the above-captioned application, applicants respectfully request that the following amendments to the claims be entered. No fees are believed due in connection with this filing beyond those fees enclosed. Should the Commissioner determine otherwise, he is authorized to debit the deficiency to ARNOLD, WHITE & DURKEE Deposit Acct. No. 01-2508/INRP:087/SHS.

I. AMENDMENTS

IN THE SPECIFICATION:

At page 1, please delete the existing title and insert therefor the following:--SYSTEMIC ADMINISTRATION OF ADENOVIRUS p53--.

At page 2, line 3, please delete the first paragraph and insert therefor the following: --This is a divisional of co-pending application Serial No. 08/145,826 filed October 29, 1993 which is a continuation-in-part of 07/960,513 filed October 13, 1992, the entire text of which is herein incorporated by reference without disclaimer. The government owns rights in the present invention pursuant to NIH grants RO1 CA 45187 and CA 16672--.

IN THE CLAIMS:

Please cancel claims 1-42 without prejudice or disclaimer.

Please add the following new claims:

--43. A method of treating a human cancer patient having a human malignancy, comprising administering regionally to said patient an amount of an adenovirus composition effective to prevent growth of malignant cells, wherein said adenovirus composition comprises an adenovirus vector construct comprising a p53 gene, dispersed in a pharmacologically acceptable solution.

44. The method of claim 43, wherein said adenoviral composition is administered to the patient by infusion over a period of time.

45. The method of claim 44, wherein said period of time is about 48 hours.

46. The method of claim 43, wherein said amount comprises between about 10^3 to about 5 x 10^{12} adenovirus particles.

47. The method of claim 46, wherein said amount comprises between about 10^3 to about 10^6 adenovirus particles.

48. The method of claim 46, wherein said amount comprises between about 1 x 10^{10} to about 5 x 10^{12} adenovirus particles.

49. The method of claim 46, wherein said amount comprises about 1 x 10^{10} virus particles.

50. The method of claim 46, wherein said amount comprises about 3 x 10^{10} virus particles.

51. The method of claim 46, wherein said amount comprises about 5 x 10^{12} adenovirus particles.

52. The method of claim 43, further comprising at least a second administration of the adenoviral composition.

53. The method of claim 52, further comprising at least a third administration of the adenoviral composition.

54. The method of claim 53, wherein the third administration occurs at least about one day after the second administration.

55. The method of claim 53, wherein the third administration occurs about one day after the second administration.

56. The method of claim 53, wherein said first, second, and third administrations are each given on three consecutive days.

57. The method of claim 43, further comprising resecting a tumor of said cancer patient.

58. The method of claim 43, wherein said resecting occurs prior to said administering.

59. The method of claim 43, wherein said adenoviral composition further comprises phosphate-buffered saline with about 1% (v/v) glycerol.

60. The method of claim 43, wherein said adenoviral composition is delivered in a volume of about 10 ml or less.

61. The method of claim 43, wherein the wild-type p53 gene is under the control of a CMV promoter.

62. The method of claim 43, wherein said growth is prevented by apoptosis.

63. A method of treating a human cancer patient comprising administering intravenously to said patient an amount of an adenovirus composition effective to prevent growth of malignant cells, wherein said adenovirus composition comprises an adenovirus vector construct comprising a p53 gene, dispersed in a pharmacologically acceptable solution.

64. The method of claim 63, wherein said adenoviral composition is administered to the patient by intravenous infusion over a period of time.

65. The method of claim 64, wherein said period of time is about 48 hours.

66. The method of claim 63, wherein said amount comprises between about 10^3 to about 5 x 10^{12} adenovirus particles.

67. The method of claim 66, wherein said amount comprises between about 10^3 to about 10^6 adenovirus particles.

68. The method of claim 66, wherein said amount comprises between about 1×10^{10} to about 5×10^{12} adenovirus particles.

69. The method of claim 63, further comprising at least a second administration of the adenoviral composition.

70. The method of claim 69, further comprising at least a third administration of the adenoviral composition.

71. The method of claim 70, wherein the third administration occurs at least about one day after the second administration.

72. The method of claim 70, wherein the third administration occurs about one day after the second administration.

73. The method of claim 70, wherein said first, second, and third administrations are each given on three consecutive days.

74. The method of claim 63, further comprising resecting a tumor of said cancer patient.

75. The method of claim 63, wherein said resecting occurs prior to said administering.

76. The method of claim 63, wherein said adenoviral composition further comprises phosphate-buffered saline with about 1% (v/v) glycerol.

77. The method of claim 63, wherein said adenoviral composition is delivered in a volume of about 10 ml or less.

78. The method of claim 63, wherein the wild-type p53 gene is under the control of a CMV promoter.

79. The method of claim 63, wherein said growth is prevented by apoptosis.

80. A method of treating a human cancer patient comprising instilling intratracheally to said patient an amount of an adenovirus composition effective to effective to prevent growth of malignant cells, wherein said adenovirus composition comprises an adenovirus vector construct comprising a p53 gene, dispersed in a pharmacologically acceptable solution.

81. The method of claim 80, wherein said adenoviral composition is administered to the patient by infusion over a period of time.

82. The method of claim 81, wherein said period of time is about 48 hours.

83. The method of claim 80, wherein said amount comprises between about 10^3 to about 5 x 10^{12} adenovirus particles.

84. The method of claim 80, wherein said amount comprises between about 10^3 to about 10^6 adenoyirus particles.

85. The method of claim 84, wherein said amount comprises between about 1 x 10^{10} to about 5 x 10^{12} adenovirus particles.

86. The method of claim 84, wherein said amount comprises about 1 x 10^{10} virus particles.

87. The method of claim 84, wherein said amount comprises about 3 x 10^{10} virus particles.

88. The method of claim 84, wherein said amount comprises about 5 x 10^{12} adenovirus particles.

89. The method of claim 80, further comprising at least a second administration of the adenoviral composition.

90. The method of claim 89, further comprising at least a third administration of the adenoviral composition.

91. The method of claim 90, wherein the third administration occurs at least about one day after the second administration.

92. The method of claim 90, wherein the third administration occurs about one day after the second administration.

93. The method of claim 90, wherein said first, second, and third administrations are each given on three consecutive days.

94. The method of claim 80, further comprising resecting a tumor of said cancer patient.

95. The method of claim 80, wherein said resecting occurs prior to said administering.

96. The method of claim 80, wherein said adenoviral composition further comprises phosphate-buffered saline with about 1% (v/v) glycerol.

97. The method of claim 80, wherein said adenoviral composition is delivered in a volume of about 10 ml or less.

98. The method of claim 80, wherein the wild-type p53 gene is under the control of a CMV promoter.

99. The method of claim 80, wherein said growth is prevented by apoptosis. --

REMARKS

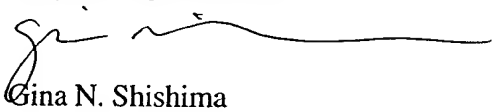
The independent claims as submitted in this Divisional Application have been previously deemed allowable in dependent form as contained in Application Serial. No. ~~08/626,678~~ 08/145,826 now subject to an interference proceeding. These allowable claims were amended to place them in independent form herein. Applicants submit that the subject matter of the independent claims as submitted in this Divisional Application is not the subject matter that is presently the basis of the interference.

Support for the amended claims may be found throughout the specification, including at: page 42, line 20; page 42, line 27; page 39, lines 26-7; page 42, line 9; page 42, line 28; page 8, line 28; page 9, line 1; page 43, line 13; page 7, lines 5-6; page 5, line 26; page 6, line 3 page 42, line 25; and page 43, line 3. Thus, no new matter has been added.

Claims 1-42 have been canceled without prejudice or disclaimer. New claims 43-99 have been added. Thus, claims 43-99 are pending.

Should the Examiner have any questions regarding this submission, he is invited to contact the undersigned at her desk telephone at (512) 418-3081.

Respectfully submitted,



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Date: October 6, 1999